

### AMENDMENTS TO THE SPECIFICATIONS

Please make the amendments listed below in the text

Page 5 line 24 of the original filing, app. & Publication 2002/0120271 ¶ [0023] last line  
.....bone-screw interface. For additional holding strength, an adhesive may be coated on the screw to plate interface and the screw to bone surfaces. To date, the only adhesives, which have the properties necessary for implants, are the cyanoacrylates. Some of the advantages of cyanoacrylate adhesives include: simple to apply, fast setup and cure, non-toxic, biocompatible, require little pre-operative preparation, are long lasting, and moisture tolerant. Ethicon Dermabond® is approved for medical use.

Page 7 line 14 of the original filing, app. & Publication 2002/0120271 ¶ [0031] line 9  
...may be removed for a proper fit. For additional holding strength an adhesive may be coated on the screw to plate interface and the screw to bone surfaces.

### Remarks/Arguments

#### ENABLEMENT IN SPECIFICATIONS

The Examiner rejects claim 6 under 35 U.S.C. 112, first paragraph, as failing to provide sufficient enablement in the specifications. The Examiner specifically cites that the specifications do not describe the type of adhesive material and the method of use.

The amendment is listed above.

**Claim rejections 35 USC 102(b)**

The examiner rejects claims 1, 3, 4, 12, 14, 27, and 28 as being anticipated by Tornier (U. S. Pat. No. 4,488,543). Figs. 1-3 of Tornier show a bone stabilizing system having all of the limitations as recited in the above listed claims, including:

The examiner recites from (4,488,543)

A plate 2, Two or more bone screws 3, Each with a threaded bone shank portion and unthreaded, tapered plate shank portion 3a which inherently makes an “interference” fit with the corresponding tapered holes 6 in the plate.

Note in Fig 3 that since a portion of the tapered screw 3a extends below the bottom surface of the plate, such portion would inherently extend into the bone in “interference”

Each of the features and differences of patent (4,488,543) and application 10/083,332 are listed and discussed under the separate sections:

**CONICAL SHAPED SCREW HEADS PROTRUDING INTO THE BONE**

**MACHINING IN THE BONE**

**LOCKING TAPER**

**FAILURE MODES**

**THE PLATE**

**THE DISK**

**CONICAL SHAPED SCREW HEADS PROTRUDING INTO THE BONE**

4,488,543 As stated in col. 2 line 31- “ each screw having the shape of the head 3a of each screw 3 is a truncated conical shape and its dimensions are such that it is complimentary with hole 6 (plate holes) in a shape of a truncated cone which is able to be used as a housing for it”

10/083,332 page 6 lines 12 – 15 & 19 - 20;

2002/0120271 ¶ 0027 lines 3 – 7 & lines 18 - 19 As shown in FIGS. 7, 8, 9, and 10, the bone screw also has a section 22, tapered 17, or cylindrical 18, at the unthreaded portion

of the shank, which engages the bone holes 15 or 16. The screw also has a tapered section 25 or a cylindrical section 26 that engages the plate holes 13 or 14. The tapered shank portion 22 extends into the vertebral bone, compressing the bone hole 15 or 16.

### **Response to the conical shaped screw heads protruding into the bone**

The bone stabilizing system of claim 1, wherein the interference fit portion of the bone screws contain one or more locking tapers, which extend into the bone and engage mating tapers in the bone.

10/083,332 also specifies an optional cylindrical interference fit in the plate or bone 4,488,543 does not claim a taper extended into the bone

### **MACHINING IN THE BONE**

From the claims of Application 10/083,332

(1a) (previously amended) a plate shank portion, a threaded portion, and a bone shank portion extending through the plate holes and machined and threaded holes in the bone into the underlying bone for a distance of 1 mm or greater, and

(14b) (previously amended) machining holes in the bone segments for the purpose of retaining the engagement of the bone screws and retaining fixation of the plate to the bones, and

(14c)(previously amended) placing the screws, with a shank portion and a head portion configured and sized to be affixed by an interference fit within the plate hole and also affixed within a portion of the machined holes in the bone.

(27) (previously amended) A bone fixation device using a plate with holes and screws, where the screws have a threaded portion and an unthreaded portion of a shank extending through the plate holes and extending into machined holes in the underlying bone with an interference fit, for the purpose of fixing one bone segment with respect to one or more other bone segments or with respect to an implant.

### **Remarks of machining in the bone**

Patent 4,488,543 column 1 lines 10 to 11 “..screws intended to be inserted into the bone..” Patent 4,488,543 does not mention or imply machined holes in the bone.

## **LOCKING TAPER**

A locking taper has an angle of taper that is less than 6 degrees. The shank is so firmly seated in its socket that there is considerable frictional resistance to any force tending to turn it.

In application 10/083,332 page 6 lines, 19 - 20 The screws are specified as screws that have a locking taper and the taper extends very specifically into the bone. The locking taper is used to eliminate the added complexity of the disk of Patent (4,488,543).

Application 10/083,332 page 3 lines 9 - 11; & 2002/0120271 ¶ [0007] lines 10 - 14  
“In the present invention, particular embodiments are described below; these embodiments improve screw strength and lock the screw within the bone by extending a tapered unthreaded section of the screw shank into the bone”.

## **Remarks of the locking taper**

Patent 4,488,543 column 2 lines 36 to 40 does not mention or imply that it is a locking taper, in fact it requires the additional “screw 9 which facilitates attachment of disk 11.” To hold the screws from unscrewing. Clearly, the screws were not intended to be self-locking.

## **FAILURE MODES**

4,488,543 implies a tap drill for threading the hole, but it does not specify nor imply the machining of the tapered holes in the bones. To get maximum stiffness of the construct, it is necessary to maximize the contact surface areas between the screw head and the plate hole. Since the screw is angled, the screw head must be longer than the plate thickness. This length causes a part of the screw head to protrude beneath the plate.

**Remarks of the failure modes 4,488,543 Fig. 3** A portion of the bone must be displaced, to allow space for the part of the screw head protruding beneath the bottom of the plate hole.

There are four possibilities of places to which the excess bone material could move:

1. Up the annulus between the screw and the plate hole. This would leave residue in the annulus and not allow seating the head in the hole.
2. Down along the bone thread. This would leave residue in the threads and would not allow seating the head in the hole.
3. Into the space between the plate and bone. This would place residue in the space.
4. Compress the bone volume in place.

Bones are stiff and cannot be compacted or extruded.

Figure 3 of 4,488,543 shows the highly stressed first thread is near the shear plane of the of the plate-bone interface

The additional force required on the bone screw heads while installing to compress the taper into the bone will strip the bone threads or the torque will break the screw at the first thread or the threads will be stripped off the screw. Extruding into first thread and blocking further advance in to the hole.

Application page 3 lines 3-6; & 2002/0120271 ¶ [0007] lines 1 – 7  
(Prior technology) “A second point of fixation results from the screw portion fixed within the bone. This produces a stress raiser of greatest stress, just below the screw attachment at the plate, rod or other implant. This is the area of most frequent screw breakage observed in clinical practice and biomechanical testing. This area of screw breakage is well known to those practiced in the art”.

## **THE PLATE**

Patent 4,488,543, column 2, lines 11-13 “is widened and defines or lies in a plain which forms, with the plane of the rest of the plate, an angle  $\theta$  between 160 to 175 degrees”.

Patent 4,488,543 Claim 1 column 3, lines 9 and 10

“Said wider end defining a plane which forms, with the plain of the rest of said plate” ...

#### **Remarks of the plate**

This plate will not fit into the space of the plate of the present application.

Patent 4,488,543 is a special purpose plate configured to only to hold, a fractured femur leg bone (a long bone) with a plate which transitions from a narrow plate to a wider plate at the end, configured to hold it to the femoral neck or to attach to the femur condyle. This plate could not be modified to replace a vertebral plate. This device appears to be good for its intended purpose of stabilizing long bones.

Application 10/083,332 and Publication 2002/0120271 Figs. 8 & 10; These figures clearly show that the holes in the plate and in the bone screw are distinct and different.

#### **THE DISK**

Patent 4,488,543 Column 2 line 37 – 42 “The disk 11 has centrally between the three holes a diameter which partially covers each of heads 3a of screws 3 to assure their being held in corresponding holes 6” (plate holes). “This arrangement Prevents, therefore, the backward movement of screws 3 out of holes 6 during the compression under the load of the fracture”.

#### **Remarks of the disk**

The necessity of the disk; “screws 3, to assure their being held in corresponding holes 6” (plate holes).

Application 10/083,332 uses locking tapers to avoid the need for complication such as disk 11 and screw 9 This shows that the screws are not intended to be locking tapers.

The disk traps the screw head after partial unscrewing.

## **SUMMARY OF THE REMARKS**

Clearly, the cone shaped head of the screw of Patent 4,488,543 would not lead one skilled in the art, to machine a tapered hole in the bone. The tapered hole in the plate is machined accurately during manufacturing of the plate. Previously the surgeon implanting the device did not have a taper drill or reamer with his surgery instruments. 4,488,543 implies a tap drill for threading the hole, but it does not specify nor imply the machining of the tapered holes in the bones. One skilled in the art would most likely shorten the conical head, sacrificing the surface area of the screw shank to remove the part of the head protruding beneath the plate. Because of the stiffness and hardness of the bone, it would not conform to the screw shank.

Application 10/083,332 provides for the holes to be machined so the tapered or cylindrical screw head seat securely in the bone with a controlled amount of interference. Bones are stiff and cannot be compacted or extruded. The tapered section or cylindrical section at the unthreaded portion of the shank engages the bone holes 15 or 16.

## **DOUBLE PATENTING**

The Examiner rejects claims 1, 3, 4, 6, 12, 27, and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U. S. Patent 6,656,181 (Dixon, Hackman).

In response to this provisional rejection based upon double patenting, a terminal disclaimer in compliance with 37 CFR § 1.321 (c) is submitted with this report. As the U. S. Patent 6,656,181 is commonly owned with this application. It is believed that this submission overcomes the provisional rejection accordingly.



**TERMINAL DISCLAIMER TO OBVIATE  
A DOUBLE PATENTING REJECTION (37 C.F.R. § 1.321(c))**

**Identification of Persons Making This Disclaimer**

We, represent that we are the inventors and applicants of this invention.

**FEE PAYMENT**

Attached is a check in the amount of \$110 of which includes \$55 for this fee.

A duplicate of this paper is attached.

**SEND CORRESPONDENCE TO**

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**CHAIN OF TITLE FROM THE PRESENT INVENTION**

**U.S. APPLICATIONS AND PATENTS**

	METHOD AND DEVICE UTILIZING TAPERED SCREW SHANKS FOR SPINAL STABILIZATION	METHOD AND DEVICE FOR USING EXTENDED <i>INTERFERENCE FIT</i> SCREW SHANKS FOR SPINAL STABILIZATION.
PROVISIONAL #	60/252,676	60/271,782
DATE FILED	NOV. 22, 2000	FEB. 27, 2001
APPLICATION. #	09/996,858	10/083,332
DATE FILED	NOV. 20, 2001	FEB. 25 2002
PUBLICATION #	US 2002/0082603	2002/0120271
DATE PUBLISHED	JUN. 27, 2002	AUG. 9, 2002
PATENT #	6,656,181	PENDING
GRANTED	DEC. 2, 2003	

As the below named inventors, we hereby declare that:

### INVENTORSHIP IDENTIFICATION


Our residence, post office address and citizenship are as stated below, next to our names. We believe that we are the original first and joint inventors of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### SPECIFICATION IDENTIFICATION

The amendments to the specifications, are attached

### SIGNATURES

Dr. Robert A. Dixon applicant and inventor 50% owner

Inventor's signature: 

Date Aug. 23, 2004

Country of Citizenship US

Residence. Powell, Ohio 43065

Post Office Address, 10577 Durham Place, Powell, OH 43065

Donald J. Hackman applicant and inventor 50% owner

Inventor's signature

Date. August 23, 2004



Country of Citizenship US

Residence

Post Office Address, 4399 Kirkham Road, Columbus, OH 43221

**Petition for Extension of Time Under 37 CFR 1.136(a):**

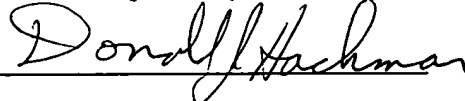
Enclosed:

- 1 copy and 1 duplicate PTO/SB/22 signed by Robert A Dixon.
- 1 copy and 1 duplicate PTO/SB/22/signed by Donald J Hackman.
- 1 check for \$110 including \$55 for this time extension of 1 month.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted

BY



Date

8-25-2009

Donald J. Hackman, Inventor/Applicant